## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): D. Courtois, et al.

Appl. No.: 10/595,894

Conf. No.: 8671

Filed: July 24, 2006

Title: FOOD COMPOSITION COMPRISING GLUCOSAMINE

Art Unit: 1655

Examiner: M. L. McCormick

Docket No.: 112701-735

## AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

## I hereby state as follows:

1. My experience and qualifications are as follows:

Chemical Engineer, specialized in Phytochemistry. I have a scientific background in extraction, purification, isolation and identification of plant bioactive metabolites completed by chemical analytical knowledge. This expertise was acquired with a first experience in Pharmaceutical Industry followed by a second one at Nestlé's Company, in our Research Center.

Scientific activities developed in the Center deal with selection/breeding, cultivation and processes of plant species monitored and controlled by chemical analytical methods of relevant molecules, for which specific extraction protocols have to be carried out.

It has been the starting point for the discovery described in this invention, through the set-up of a new drying process and related analytical studies.

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

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- 3. I have reviewed the outstanding Office Action dated July 21, 2008 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the references cited therein as well as the pending claims.
- 4. The present invention is directed, in part, to products and compositions comprising glucosamine obtained from a fresh or raw plant origin and generated through the drying processes of the present disclosure. The products and compositions of the present disclosure may be used for the maintenance of joint health, or prevention, alleviation and/or treatment of osteoarthritis, or the improvement of the skin quality and prevention or restoration of age-related alterations of the skin.
- 5. Surprisingly, it has been found that free glucosamine can be formed in high amounts during the controlled drying process of the present disclosure when compared to glucosamine amounts obtained from plant material dried according to commercial drying processes or obtained from fresh (non-dried) plant material. "High amounts" of glucosamine may be understood to mean that glucosamine is present in amounts higher than traces of glucosamine and higher than amounts in corresponding fresh (non-dried) material. For example, "high amounts" of glucosamine may be understood as glucosamine that is present in amounts above 150 mg/kg dry matter of raw material, depending on the plant species and plant organ.
- 6. The drying processes of the present disclosure may involve placing harvested and cut fresh or raw plant material in an oven or an industrial dryer at a temperature below 110°C for less than one week, the temperatures and times are dependant on the plant species and/or the plant organ. In accordance with these processes, and without wishing to be bound to any theory, the high amounts of glucosamine may be formed not necessarily from the degradation of macromolecules with the subsequent release of free glucosamine but, rather, from the release of free fructose and amino acids during the drying of the plant material, followed by the first steps of a Maillard reaction.

- 7. As summarized in the Examples of the present disclosure, drying fresh or raw plant materials according to the processes disclosed in the present disclosure results in high amounts of glucosamine when compared to amounts of glucosamine obtained from commercial drying processes or fresh (non-dried) plant material. For example, Example 1 of the present specification illustrates the surprisingly high amounts of glucosamine that are achieved when the chicory of Example 1 was dried according to processes disclosed in the present specification, as opposed to commercially dried roots of chicory or fresh (non-dried) roots of chicory. Specifically, a glucosamine concentration of 900 mg/kg dry weight was obtained from chicory prepared according to processes disclosed in the present specification. In contrast, a glucosamine concentration of only 10 mg/kg dry weight was obtained from chicory prepared by commercial drying or from fresh (non-dried) chicory.
- 8. Similarly, Example 2 of the present specification illustrates the surprisingly high amounts of glucosamine that are achieved when the carrots of Example 2 are dried according to processes disclosed in the present specification, as opposed to fresh (non-dried) carrots. Specifically, a glucosamine concentration of 190 mg/kg dry weight was obtained from carrots prepared according to processes disclosed in the present specification. In contrast, a glucosamine concentration of less than 1 mg/kg dry weight was obtained from fresh (non-dried) carrots. Therefore, both Examples 1 and 2 demonstrate that surprisingly high amounts of glucosamine may be obtained when raw or fresh plant materials are dried according to the processes of the present disclosure.
- 9. *Ecochard* fails to disclose or suggest products or compositions comprising glucosamine obtained by drying fresh or raw plant materials. Further, *Ecochard* fails to disclose or suggest wherein the glucosamine is present in the products or compositions in amounts greater than 150 mg/kg dry matter. In fact, at no place in the disclosure does *Ecochard* even recognize that surprisingly high amounts of glucosamine may be obtained when raw or fresh plant materials are dried according to the processes of the present disclosure.

- 10. Ecochard is entirely directed toward the treatment of chicory powder with conditions that melt the powder so that the powder particles are agglomerated. Ecochard does not disclose or suggest any methods by which the chicory powder is obtained, let alone disclose specific processes for drying raw or fresh plant material. Instead, Echochard simply mentions that soluble chicory powder is used to form a layer of determined thickness that may then be heated using hot air circulation at 95°C for a transit time of the order of 90 or 600 seconds in order to agglomerate the chicory powder particles. Thus, the chicory powder of Ecochard is obtained prior to the environmental conditions that allow for agglomeration of the powder particles, as previously mentioned. Because Echochard teaches only the use of chicory powder with conditions that melt the powder so that the powder particles are agglomerated and because Ecochard does not disclose products or compositions comprising glucosamine obtained by drying fresh or raw plant materials or glucosamine present in the products or compositions in amounts greater than 150 mg/kg dry matter, the products of Ecochard do not have the higher amounts of glucosamine discussed herein above or disclosed in the present application. Specifically, the products would not have glucosamine in amounts of greater than 150 mg/kg dry matter.
- 11. Fleischner fails to disclose or suggest products or compositions comprising glucosamine obtained by drying fresh or raw plant materials. Further, Fleischner fails to disclose or suggest wherein the glucosamine is present in the products or compositions in amounts greater than 150 mg/kg dry matter. In fact, at no place in the disclosure does Fleischner even recognize that surprisingly high amounts of glucosamine may be obtained when raw or fresh plant materials are dried according to the processes of the present disclosure.
- 12. Fleischner teaches a weight loss product having supplemental compositions. Specifically, Fleischner teaches a combination of ma huang extract (ephedrine alkaloids), caffeine and glucosamine sulfate that results in weight loss. The glucosamine of Fleischner is provided in the form of glucosamine sulfate and is used to block the effect of insulin, which is used to burn up stored fat. However, Fleischner does not disclose or suggest any methods by which the glucosamine sulfate is obtained, let alone disclose specific processes for drying raw or

fresh plant material. Because *Fleischner* does not teach products or compositions comprising glucosamine obtained by drying fresh or raw plant materials or glucosamine present in the products or compositions in amounts greater than 150 mg/kg dry matter, the products of *Fleischner* do not have the higher amounts of glucosamine discussed herein above or disclosed in the present application. Specifically, the products would not have glucosamine in amounts of greater than 150 mg/kg dry matter.

- 13. *Noel* fails to disclose or suggest products or compositions comprising glucosamine obtained by drying fresh or raw plant materials. Further, *Noel* fails to disclose or suggest wherein the glucosamine is present in the products or compositions in amounts greater than 150 mg/kg dry matter. In fact, at no place in the disclosure does *Noel* even recognize that surprisingly high amounts of glucosamine may be obtained when raw or fresh plant materials are dried according to the processes of the present disclosure.
- 14. *Noel* teaches a cosmetic composition comprising a cosmetic base containing an amount of a mixture of chitosan, glucosamine and at least one acid selected from the group consisting of succinic acid and gluconic acid. However, *Noel* does not disclose or suggest any methods by which the glucosamine is obtained, let alone disclose specific processes for drying raw or fresh plant material. Because *Noel* does not teach products or compositions comprising glucosamine obtained by drying fresh or raw plant materials or glucosamine present in the products or compositions in amounts greater than 150 mg/kg dry matter, the products of *Noel* do not have the higher amounts of glucosamine discussed herein above or disclosed in the present application. Specifically, the products would not have glucosamine in amounts of greater than 150 mg/kg dry matter.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing there from.

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